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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

TZUMI INNOVATIONS, LLC,

Plaintiff,

v.

MICHAEL S. REGAN, in his official capacity
as Administrator of the United States
Environmental Protection Agency,¹ and
UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY,

Defendants.

ANSWER

21 Civ. 0122 (LGS)

Defendants Michael S. Regan, in his official capacity as Administrator of the United States Environmental Protection Agency (“EPA”) and EPA (together, “Defendants”), by their attorney, Audrey Strauss, United States Attorney for the Southern District of New York, answer Plaintiff Tzumi Innovations, LLC’s (“Plaintiff”) Amended Complaint (ECF No. 27) on information and belief as follows:

¹ Michael S. Regan, who became the Administrator of the Environmental Protection Agency on March 11, 2021, is automatically substituted for former Administrator Andrew R. Wheeler as the defendant in this action. *See Fed. R. Civ. P. 25(d).*

IN ANSWER TO THE SECTION TITLED “NATURE OF THE ACTION”

1. Paragraph 1 of the Amended Complaint constitutes Plaintiff's characterization of its action to which no response is required. To the extent a response is required, deny Plaintiff's characterization.
2. Deny Paragraph 2 of the Amended Complaint, except admit that the Wipe Out! wipes are not registered as a pesticide with the EPA.
3. Paragraph 3 of the Amended Complaint constitutes Plaintiff's legal characterization to which no response is required. To the extent a response is required, deny Plaintiff's characterization. Aver that the Court concluded that “Plaintiff's argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” Opinion and Order (“ECF No. 53”) at 15.
4. Deny Plaintiff's characterization in the first clause of the first sentence of Paragraph 4 of the Amended Complaint and Plaintiff's allegation in the last sentence of Paragraph 4. Deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 4. Aver that the Court concluded that “Plaintiff's argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.
5. Admit that EPA's advisory letter to Plaintiff was dated August 29, 2020, and that EPA emailed the letter to Plaintiff and Home Depot on or about September 1, 2020. Deny that Plaintiff's characterization of the letter is complete and accurate and respectfully refer the Court to the advisory letter for a complete and accurate description of its contents.

6. Deny Plaintiff's characterization contained in Paragraph 6 of the Amended Complaint, except admit that Plaintiff and the EPA repeatedly communicated by phone and in written correspondence, including but not limited to on December 6, 2020, December 14, 2020, and December 31, 2020, regarding Plaintiff's Wipe Out! wipes, EPA's view that it appeared to be an unregistered pesticide, and EPA's request that Plaintiff voluntarily recall the product.

7. Admit the allegations contained in Paragraph 7 of the Amended Complaint.

8. Deny Plaintiff's characterization of the agreement and the Court's January 15, 2020, Order and respectfully refer the Court to the Order at ECF No. 22 for a complete and accurate description of its contents.

9. Deny the allegations contained in Paragraph 9 of the Amended Complaint, except admit that Plaintiff's counsel has sent correspondence to EPA in which counsel has asserted that Wipe Out! wipes are not a pesticide, and on December 17, 2020, Plaintiff's counsel requested a meeting with EPA to further discuss Wipe Out! wipes.

10. Deny the allegations contained in Paragraph 10 of the Amended Complaint.

11. Deny the allegations contained in Paragraph 11 of the Amended Complaint.

12. Deny the allegations contained in Paragraph 12 of the Amended Complaint.

13. Deny the allegations contained in Paragraph 13 of the Amended Complaint.

14. Deny the allegations contained in Paragraph 14 of the Amended Complaint. Aver that EPA's counsel suggested on November 20, 2020, that EPA could potentially issue a SSURO as a last resort measure to remove a violative product from the market, but that this was not EPA's preferred response.

15. Deny the allegations contained in Paragraph 15 of the Amended Complaint.

16. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 16 of the Amended Complaint. Aver that the Court dismissed Plaintiff's allegations relating to any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

17. Deny the allegations contained in Paragraph 17 of the Amended Complaint.

IN ANSWER TO THE SECTION TITLED “PARTIES”

18. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 18 of the Amended Complaint.

19. Admit the allegations contained in Paragraph 19 of the Amended Complaint.

20. Deny that Andrew R. Wheeler is the current Administrator of the EPA. Aver that Michael S. Regan became the Administrator of the Environmental Protection Agency on March 11, 2021, and that his office is at 1200 Pennsylvania Avenue, N.W., Washington, DC 20460.

IN ANSWER TO THE SECTION TITLED “JURISDICTION AND VENUE”

21. Paragraph 21 of the Amended Complaint constitutes Plaintiff's characterization of jurisdiction to which no response is required. To the extent a response is required, deny that the Court has jurisdiction over this action.

22. Paragraph 22 of the Amended Complaint constitutes Plaintiff's characterization of jurisdiction and legal argument to which no response is required. To the extent a response is required, deny.

23. Paragraph 23 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny.

24. Paragraph 24 of the Amended Complaint constitutes Plaintiff's characterization of personal jurisdiction to which no response is required.

25. Paragraph 25 of the Amended Complaint constitutes Plaintiff's characterization of venue to which no response is required.

IN ANSWER TO THE SECTION TITLED “STANDING”

26. Paragraph 26 of the Amended Complaint constitutes Plaintiff's legal argument regarding standing to which no response is required.

27. Paragraph 27 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny.

IN ANSWER TO THE SECTION TITLED “FACTUAL BACKGROUND: A. THE PLAINTIFF AND THE PRODUCT”

28. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 28 of the Amended Complaint.

29. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 29 of the Amended Complaint.

30. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of Paragraph 30 of the Amended Complaint. Deny Plaintiff's characterization contained in the second sentence of Paragraph 30 of the Amended Complaint.

31. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 31 of the Amended Complaint.

32. Deny that Plaintiff's characterization of the label in Paragraph 32 of the Amended Complaint is complete and accurate and respectfully refer the Court to the label for a complete and accurate description of its contents.

33. Deny that Plaintiff's characterization of the label in Paragraph 33 of the Amended Complaint is complete and accurate and respectfully refer the Court to the label for a complete and accurate description of its contents.

34. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 34 of the Amended Complaint.

35. Deny the allegations contained in Paragraph 35 of the Amended Complaint.

**IN ANSWER TO THE SECTION TITLED “FACTUAL BACKGROUND: B.
ALLOCATION OF REGULATORY RESPONSIBILITY”**

36. Paragraph 36 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny Plaintiff's characterization and respectfully refer the Court to the Federal Food, Drug, and Cosmetic Act (“FFDCA”) for a complete and accurate description of its contents. Aver that the Court concluded that “Plaintiff's argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

37. Paragraph 37 of the Amended Complaint constitutes Plaintiff's legal characterization, to which no response is required. To the extent a response is required, deny Plaintiff's characterization and respectfully refer the Court to the FFDCA for a complete and accurate description of its contents. Aver that the Court concluded that “Plaintiff's argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

38. Paragraph 38 of the Amended Complaint constitutes Plaintiff's legal characterization, to which no response is required. To the extent a response is required, deny Plaintiff's characterization and respectfully refer the Court to the Federal Insecticide, Fungicide,

and Rodenticide Act (“FIFRA”), *see* 7 U.S.C. § 136, for a complete and accurate description of its contents. Aver that the Court concluded that “Plaintiff’s argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

39. Paragraph 39 of the Amended Complaint constitutes Plaintiff’s legal characterization, to which no response is required. To the extent a response is required, deny Plaintiff’s characterization and respectfully refer the Court to the FFDCA and FIFRA for a complete and accurate description of their contents. Aver that the Court concluded that “Plaintiff’s argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

40. Paragraph 40 of the Amended Complaint constitutes Plaintiff’s legal characterization, to which no response is required. To the extent a response is required, deny Plaintiff’s characterization and respectfully refer the Court to the FIFRA, 7 U.S.C. § 136(t) & (u), for a complete and accurate description of its contents. Aver that the Court concluded that “Plaintiff’s argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

41. Paragraph 41 of the Amended Complaint constitutes Plaintiff’s legal argument, to which no response is required. To the extent a response is required, admit. Aver that the Court concluded that “Plaintiff’s argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

42. Paragraph 42 of the Amended Complaint constitutes Plaintiff’s legal argument and characterization, to which no response is required. To the extent a response is required, deny

Plaintiff's characterization and respectfully refer the Court to FIFRA, 7 U.S.C. § 136(t), for a complete and accurate description of its contents. Aver that the Court concluded that "Plaintiff's argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive." ECF No. 53 at 15.

43. Paragraph 43 of the Amended Complaint constitutes Plaintiff's legal argument and characterization, to which no response is required. To the extent a response is required, deny Plaintiff's characterization and respectfully refer the Court to 40 C.F.R. §152.6(c) for a complete and accurate description of its contents. Aver that the Court concluded that "Plaintiff's argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive." ECF No. 53 at 15.

44. Paragraph 44 of the Amended Complaint constitutes Plaintiff's legal argument and characterization, to which no response is required. To the extent a response is required, deny Plaintiff's characterization and respectfully refer the Court to the statute, regulation, and Memorandum of Understanding ("MOU") for a complete and accurate description of their contents. Aver that the Court concluded that "Plaintiff's argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive." ECF No. 53 at 15.

45. Paragraph 45 of the Amended Complaint constitutes Plaintiff's legal argument and characterization, to which no response is required. To the extent a response is required, deny Plaintiff's characterization and respectfully refer the Court to the MOU for a complete and accurate description of its contents. Admit that Plaintiff correctly quoted the block-quoted text. Aver that the Court concluded that "Plaintiff's argument that EPA should not regulate [Wipe Out! wipes]

because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

46. Deny the first clause of the sentence contained in Paragraph 46 because “this division of responsibility” is vague and ambiguous. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in the second clause of the sentence. Aver that the Court concluded that “Plaintiff’s argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

47. Deny Plaintiff’s characterization in Paragraph 47 of the Amended Complaint and respectfully refer the Court to the website for a complete and accurate description of its contents. *See* <https://www.epa.gov/coronavirus/why-arent-hand-sanitizers-listed-list-n> (last visited on August 27, 2021). Admit that Plaintiff correctly quoted the text in Paragraph 47. Aver that the Court concluded that “Plaintiff’s argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

48. Deny Plaintiff’s characterization in Paragraph 48 of the Amended Complaint and respectfully refer the Court to the website for a complete and accurate description of its contents. *See* <https://www.fda.gov/cosmetics/cosmetic-products/disposable-wipes> (last visited on August 27 2021). Admit that Plaintiff correctly quoted the text in Paragraph 48. Aver that the Court concluded that “Plaintiff’s argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

49. Deny because Plaintiff's characterization of "this division of responsibility" is vague and ambiguous and Defendants are unaware of what source Plaintiff is referencing, except admit that EPA's registration requirement for pesticides excludes substances intended and used solely to prevent, destroy, repel, or mitigate microorganisms in or on living humans and animals. Aver that the Court concluded that "Plaintiff's argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive." ECF No. 53 at 15.

IN ANSWER TO THE SECTION TITLED "FACTUAL BACKGROUND: C. HAND WIPES CONTAINING BENZALKONIUM CHLORIDE ARE REGULATED BY THE FDA"

50. Paragraph 50 of the Amended Complaint constitutes Plaintiff's legal characterization, to which no response is required. To the extent a response is required, deny Plaintiff's characterization and respectfully refer the Court to the source Plaintiff is summarizing for a complete and accurate description of its contents. *See* <https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs> (lasted visited on August 27, 2021). Aver that the Court concluded that "Plaintiff's argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive." ECF No. 53 at 15.

51. Paragraph 51 of the Amended Complaint constitutes Plaintiff's legal characterization, to which no response is required. To the extent a response is required, deny Plaintiff's characterization and respectfully refer the Court to the source Plaintiff is summarizing for a complete and accurate description of its contents. *See* <https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs> (last visited on August 27, 2021). Aver that

the Court concluded that “Plaintiff’s argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

52. Paragraph 52 of the Amended Complaint constitutes Plaintiff’s legal characterization, to which no response is required. To the extent a response is required, deny Plaintiff’s characterization and respectfully refer the Court to the source Plaintiff is summarizing for a complete and accurate description of its contents. *See* <https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs> (last visited on August 27, 2021). Aver that the Court concluded that “Plaintiff’s argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

53. Paragraph 53 of the Amended Complaint constitutes Plaintiff’s legal characterization, to which no response is required. To the extent a response is required, deny Plaintiff’s characterization and respectfully refer the Court to 59 FR 31402 (June 11, 1994) for a complete and accurate description of its contents. *See* <https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs> (last visited on August 27, 2021). Aver that the Court concluded that “Plaintiff’s argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive.” ECF No. 53 at 15.

**IN ANSWER TO THE SECTION TITLED “FACTUAL BACKGROUND: D,
EXECUTIVE ORDER 13892-PROMOTING THE RULE OF LAW THROUGH
TRANSPARENCY AND FAIRNESS IN CIVIL ADMINISTRATIVE ENFORCEMENT
AND ADJUDICATION”**

54. Paragraph 54 of the Amended Complaint constitutes Plaintiff's legal characterization, to which no response is required. To the extent a response is required, deny that Plaintiff correctly quoted the text and respectfully refer the Court to Executive Order 13892, 84 FR 55239 (Oct. 9, 2019), for a complete and accurate description of its contents. Aver that Executive Order 13892 has been revoked, *see* Executive Order 13992, 86 FR 7049 (Jan. 20, 2021), and that the Court dismissed Plaintiff's claim pertaining to Executive Order 13892. *See* ECF No. 53 at 13.

**IN ANSWER TO THE SECTION TITLED “FACTUAL BACKGROUND: E. THE EPA
THREATENS ENFORCEMENT”**

55. Admit the allegations contained in Paragraph 55 of the Amended Complaint.

56. Admit that EPA may send a warning letter under certain circumstances set forth in FIFRA sections 14(a)(2), 14(a)(4), and 9(c)(3). Deny all other allegations contained in Paragraph 56 of the Amended Complaint.

57. Admit that EPA may choose to seek civil monetary penalties against the alleged violator, upon a hearing after proper notice. Deny all other allegations contained in Paragraph 57 of the Amended Complaint.

58. Admit that EPA may choose to seize the unregistered product under certain circumstances. Deny all other allegations contained in Paragraph 58 of the Amended Complaint.

59. Admit that EPA may choose to issue a SSURO, which requires the seller or distributor to stop selling or using, or to remove, the product at issue. Deny all other allegations contained in Paragraph 59 of the Amended Complaint.

60. Paragraph 60 of the Amended Complaint constitutes Plaintiff's legal characterization to which no response is required. To the extent a response is required, deny Plaintiff's characterization and respectfully refer the Court to EPA's FIFRA Inspection Manual for a complete and accurate description of its contents. *See* <https://www.epa.gov/sites/default/2014-01/documents/fiframanual.pdf> (last visited on August 27, 2021). Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

61. Admit that EPA's advisory letter to Plaintiff was dated August 29, 2020, and that EPA emailed the letter to Plaintiff on or about September 1, 2020. Deny Plaintiff's characterization of the letter is complete and accurate and respectfully refer the Court to the advisory letter for a complete and accurate description of its contents. Aver that the advisory letter also addressed Plaintiff's devices.

62. Deny Plaintiff's characterization contained in Paragraph 62 of the Amended Complaint and respectfully refer the Court to the advisory letter for a complete and accurate description of its contents.

63. Deny Plaintiff's characterization contained in the first sentence of Paragraph 63 of the Amended Complaint and respectfully refer the Court to the printout from Home Depot's website for a complete and accurate description of its contents. Admit that Plaintiff correctly quoted the one sentence it provided. Regarding the second sentence in Paragraph 63, admit that

one of Plaintiff's employees drafted the language and deny knowledge or information sufficient to form a belief as to the truth of the allegation regarding whether the employee initially did not realize the language was inaccurate.

64. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 64 of the Amended Complaint regarding what Plaintiff concluded, but admit the remaining allegations contained in Paragraph 64.

65. Deny that all misleading claims were removed from Home Depot's website by September 2020. Aver that even after September 2020 the product Questions and Answers and consumer reviews sections of the website still mentioned that Wipe Out! wipes could be used on surfaces. Admit that by September 2020 the product description section of the website did not refer to surfaces

66. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 66 of the Amended Complaint.

67. Admit that by early September 2020 the Home Depot website contained the phrase “[c]lean your hands with bleach-free wipes to keep dirt and germs away and leave behind a clean Fresh scent.” Respectfully refer the Court to Home Depot's website description of Plaintiff's Wipe Out! wipes for a complete and accurate description of its contents.

68. Deny Plaintiff's characterization contained in Paragraph 68 of the Amended Complaint.

69. Deny Plaintiff's characterization contained in the first sentence of Paragraph 69 of the Amended Complaint, although admit that EPA asked Plaintiff to voluntarily recall its Wipe Out! wipes that appeared to be unregistered pesticides and its pesticide devices that appeared to be

misbranded. Aver that with respect to the Wipe Out! wipes and devices, EPA requested that Plaintiff export them to another country, relabel them, or dispose of them. Further aver that EPA requested that Plaintiff provide a comprehensive and curative compliance plan and additional information about Plaintiff's products, which Plaintiff has not provided to date. Deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in the second sentence of Paragraph 69 of the Amended Complaint.

70. Admit the allegations contained in Paragraph 70 of the Amended Complaint.

71. Admit that the label Plaintiff attached as Exhibit 1A to the Amended Complaint is the label that Plaintiff shared with EPA on September 9, 2020. Deny knowledge or information sufficient to form a belief as to the truth of the allegations regarding how many units of Wipe Out! wipes bear that label.

72. Admit that EPA sent Plaintiff an email on September 10, 2020. Deny Plaintiff's characterization of that email and the Wipe Out! label and respectfully refer the Court to the email and Wipe Out! label for a complete and accurate description of their contents.

73. Admit that on September 15, 2020, Plaintiff sent EPA a revised label that added "HAND WIPES" in unbolded print on the front label panel and removed the language "Use it Anytime, Anywhere," and respectfully refer the Court to the label for a complete and accurate description of its contents. Deny that Plaintiff provided this revised label in response to any request by EPA for a label change.

74. Deny Plaintiff's characterization of its conversations with EPA. Aver that the label Plaintiff submitted to EPA was neither a label for a registered product submitted through appropriate procedures, nor was it an element of a comprehensive and curative compliance plan.

75. Deny the allegations contained Paragraph 75 of the Amended Complaint, except deny knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's knowledge.

76. Admit that EPA was concerned with the phrase "Use it Anytime, Anywhere" on the label for Wipe Out! wipes, although deny that this was EPA's only concern. Deny the remaining allegations contained in Paragraph 76 of the Amended Complaint.

77. Paragraph 77 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, respectfully refer the Court to the regulations for a complete and accurate description of their contents.

78. Admit that Plaintiff's counsel sent EPA's counsel an email on December 6, 2020. Deny Plaintiff's characterization of that email and respectfully refer the Court to the email for a complete and accurate description of its contents.

79. Admit that Plaintiff's counsel sent EPA's counsel an email attaching a letter on December 14, 2020. Deny Plaintiff's characterization of that letter and respectfully refer the Court to the letter for a complete and accurate description of its contents.

80. Admit that Plaintiff's counsel and EPA's counsel had a phone conversation on December 17, 2020, that lasted for over one hour. Deny the second sentence of Paragraph 80 of the Amended Complaint. Aver that EPA's counsel requested that Plaintiff provide EPA by January 8, 2021, with any evidence that Plaintiff was attempting to address EPA's FIFRA compliance concerns so that EPA could assess whether Plaintiff had any real interest in addressing EPA's concerns.

81. Deny the allegations contained in the first sentence of Paragraph 81 of the Amended Complaint. Aver that EPA's counsel informed Plaintiff's counsel that she needed to discuss his request for another meeting with her colleague. Deny Plaintiff's characterization contained in the second sentence of Paragraph 81 and respectfully refer the Court to the email for a complete and accurate description of its contents.

82. Admit that Plaintiff's counsel wrote to the EPA again on December 31, 2020. Deny Plaintiff's characterization of that letter and respectfully refer the Court to the letter and all of Plaintiff's and EPA's communications for a complete and accurate description of their contents.

83. Deny the allegations contained in Paragraph 83 of the Amended Complaint.

84. Deny the allegations contained in Paragraph 84 of the Amended Complaint. Aver that the Court concluded that "Plaintiff's argument that EPA should not regulate [Wipe Out! wipes] because it is a hand sanitizer regulated exclusively by the FDA is not persuasive." ECF No. 53 at 15.

85. Deny the allegations contained in Paragraph 85 of the Amended Complaint.

86. Deny the allegations contained in Paragraph 86 of the Amended Complaint.

87. Deny the allegations contained in Paragraph 87 of the Amended Complaint.

88. Deny the allegations contained in Paragraph 88 of the Amended Complaint. Aver that Plaintiff has not proposed any comprehensive curative measures or provided additional information about Plaintiff's products for EPA's consideration, despite EPA's requests. Further aver that Plaintiff's focus has been on arguing that Wipe Out! wipes can only be regulated by the FDA, an argument which the Court has found is not persuasive. *See* ECF No. 53 at 15.

89. Deny the allegations contained in Paragraph 89 of the Amended Complaint.

90. Deny the allegations contained in Paragraph 90 of the Amended Complaint.

91. Deny knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 91 of the Amended Complaint.

IN ANSWER TO THE SECTION TITLED “FACTUAL BACKGROUND: F. TZUMI WILL SUFFER IRREPARABLE INJURY FROM A RECALL OR SSURO”

92. Deny knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 92 of the Amended Complaint. Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

93. Deny knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 93 of the Amended Complaint. Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

94. Deny knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 94 of the Amended Complaint. Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

95. Deny knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 95 of the Amended Complaint. Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

96. Paragraph 96 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 96 of the Amended Complaint. Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

97. Paragraph 97 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 97 of the Amended Complaint. Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

98. Paragraph 98 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 98 of the Amended Complaint. Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

99. Paragraph 99 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 99 of the Amended Complaint.

100. Paragraph 100 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 100 of the Amended Complaint.

101. Paragraph 101 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny knowledge or information sufficient to form a belief as to the truth of allegations contained in Paragraph 101 of the Amended Complaint.

IN ANSWER TO THE SECTION TITLED “COUNT I: VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT” (ALLEGEDLY ARBITRARY AND CAPRICIOUS DETERMINATION)

102. Defendants incorporate by reference their responses to Paragraphs 1 through 101 of the Amended Complaint as if fully set forth herein.

103. Paragraph 103 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny.

104. Paragraph 104 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, respectfully refer the Court to 5 U.S.C. § 706 for a complete and accurate description of its contents.

105. Paragraph 105 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, respectfully refer the Court to 5 U.S.C. § 705 for a complete and accurate description of its contents.

106. Paragraph 106 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, respectfully refer the Court to FIFRA for a complete and accurate description of its contents.

107. Paragraph 107 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny Plaintiff's characterization.

108. Deny the allegations contained in Paragraph 108 of the Amended Complaint.

109. Deny the allegations contained in Paragraph 109 of the Amended Complaint.

110. Deny the allegations contained in Paragraph 110 of the Amended Complaint.

111. Deny the allegations contained in Paragraph 111 of the Amended Complaint.

**IN ANSWER TO THE SECTION TITLED “COUNT II: VIOLATION OF THE
ADMINISTRATIVE PROCEDURE ACT” (ALLEGEDLY UNLAWFUL CHANGE IN
REGULATORY POSITION)**

112. The Court dismissed Count II of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

113. The Court dismissed Count II of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

114. The Court dismissed Count II of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

115. The Court dismissed Count II of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

116. The Court dismissed Count II of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

117. The Court dismissed Count II of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

118. The Court dismissed Count II of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

119. The Court dismissed Count II of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

120. The Court dismissed Count II of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

**IN ANSWER TO THE SECTION TITLED “COUNT III: VIOLATION OF THE
ADMINISTRATIVE PROCEDURE ACT” (ALLEGEDLY UNLAWFUL
RULEMAKING)**

121. The Court dismissed Count III of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

122. The Court dismissed Count III of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

123. The Court dismissed Count III of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

124. The Court dismissed Count III of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

125. The Court dismissed Count III of the Amended Complaint. *See* ECF No. 53 at 12-13. Therefore, no response is required.

**IN ANSWER TO THE SECTION TITLED “COUNT IV: VIOLATION OF EXECUTIVE
ORDER 13892”**

126. The Court dismissed Count IV of the Amended Complaint. *See* ECF No. 53 at 13. Therefore, no response is required.

127. The Court dismissed Count IV of the Amended Complaint. *See* ECF No. 53 at 13. Therefore, no response is required.

IN ANSWER TO THE SECTION TITLED “COUNT V: DECLARATORY JUDGMENT-VIOLATION OF FIFRA”

128. Defendants incorporate by reference their responses to Paragraphs 1 through 127 of the Amended Complaint as if fully set forth herein.

129. Paragraph 129 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny Plaintiff's characterization. Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

130. Paragraph 130 of the Amended Complaint constitutes Plaintiff's legal argument and characterization of its action to which no response is required. To the extent a response is required, deny Plaintiff's characterization.

131. Paragraph 131 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny Plaintiff's characterization. Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

132. Deny the allegations contained in Paragraph 132 of the Amended Complaint. Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

**IN ANSWER TO THE SECTION TITLED “COUNT VI: DECLARATORY
JUDGMENT-DUE PROCESS”**

133. Defendants incorporate by reference their responses to Paragraphs 1 through 132 of the Amended Complaint as if fully set forth herein.

134. Paragraph 134 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny Plaintiff's characterization. Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

135. Paragraph 135 of the Amended Complaint constitutes Plaintiff's legal argument and characterization of its action to which no response is required. To the extent a response is required, deny Plaintiff's characterization.

136. Paragraph 136 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny Plaintiff's characterization. Aver that the Court concluded that Plaintiff's argument that EPA should not regulate Wipe Out! wipes because they are hand sanitizers regulated exclusively by the FDA was not persuasive. *See* ECF No. 53 at 15.

137. Paragraph 137 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny Plaintiff's characterization.

138. Paragraph 138 of the Amended Complaint constitutes Plaintiff's legal argument to which no response is required. To the extent a response is required, deny Plaintiff's characterization. Aver that the Court concluded that Plaintiff's argument that EPA should not regulate Wipe Out! wipes because they are hand sanitizers regulated exclusively by the FDA was

not persuasive. *See* ECF No. 53 at 15. Aver that the Court dismissed Plaintiff's allegations relating any threat by EPA to issue a SSURO. *See* ECF No. 53 at 9.

139. Deny the allegations contained in Paragraph 139 of the Amended Complaint.

IN ANSWER TO THE SECTION TITLED “PRAYER FOR RELIEF”

1. The remainder of the Complaint, including Paragraphs A through M, consists of Plaintiff's prayer for relief, to which no response is required. To the extent a response is required, deny that Plaintiff is entitled to the relief it seeks or to any relief. Aver that much of the relief pertains to claims that the Court has dismissed. *See* ECF No. 53 at 9, 12-13, 15.

DEFENSES

FIRST DEFENSE

Plaintiff fails to state a claim upon which relief can be granted.

SECOND DEFENSE

The Administrator's or Agency's final decision is not arbitrary or capricious or otherwise contrary to law and is supported by substantial evidence.

THIRD DEFENSE

This Court lacks subject matter jurisdiction.

FOURTH DEFENSE

The Amended Complaint fails to identify a final agency action.

FIFTH DEFENSE

Defendants reserve the right to amend this answer to assert any other matter that constitutes an avoidance or affirmative defense under Rule 8(c) of the Federal Rules of Civil Procedure.

WHEREFORE Defendants respectfully requests that the Court: (1) dismiss the Amended Complaint in its entirety with prejudice; (2) enter judgment in favor of Defendants; and (3) grant such further relief as the Court deems just and proper.

Dated: New York, New York
August 27, 2021

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